

REMARKS

Applicants respectfully request reconsideration of the present application.

**I. Disposition of the claims**

Claims 17-20 and 24-28 are pending.

Claims 1-16 and 21-23 are/were canceled without prejudice or disclaimer.

Claims 17-20 and 24-28 are currently amended. Support for these amendments is believed obvious from the record.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate status identifier.

**II. Telephonic Interview with Examiner Jeffrey S. Eberhard and the Priority Document**

In an interview on September 4, 2007, with Examiner Eberhard, Sean A. Passino (45,943) and the Examiner discussed his requirement for an English language translation of the Japanese language priority document. See Office action, para. 1. The Examiner indicated that he only required a certified copy of the Japanese application or the location of the application where this document may be found. Accordingly, the Office action was read as if the Office action reflected the results of the interview.

The certified copy of the prior Japanese application is in the Image File Wrapper in PAIR of the parent application (U.S. application no. 09/582,926). Thus, it is believed that the present requirement is met and checking box 12a2 on Form PTO-325 is appropriate.

**III. Requirement for Substitute Specification**

The substitute specification filed March 12, 2004 has not been entered, because (1) the amendments are presented in a separate document as an addendum to the original specification and (2) the number and nature of the amendments render it difficult to consider the application, and to arrange the paper for printing and copying. Office action, para. 2. The

objection requires a rewrite of the specification to consist of a single document with amended text clearly annotated as such, and readily differentiated from text of the original version. Office action, p. 2. Along these lines, the objection noted that reference numbering in the amendments to the specification is not completely consistent with the reference numbering in the originally submitted version of the specification.

It is submitted that appropriate correction was made in the clean and Marked-Up copies of the Specification, which are attached and considered part of this amendment.

**IV. Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 24-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Office action, para. 4. The three separate grounds will be addressed under three separate headers in the order enumerated in the Office action.

**A. Claim 24**

Claim 24 is rejected for the following reasons:

Claim 24 reads "a method of suppressing bioactive substance initial burst.. ." None of the embodiments taught in the application specifically define "suppression" in this context, and there is no means taught for assessing said suppression. Therefore, the claim is rejected for failure to establish criteria for assessing the extent of suppression of "bioactive initial burst ..." in one particular embodiment over another.

Office action, para. 4. The Examiner is directed to the discussion concerning both Table 2 at page 54 and Table 3 at page 56 of the as-filed specification, and, e.g., Example 9 and comparative example 2 at pages 49-50 of the as-filed specification. It is submitted that one of ordinary skill in the art, as evidenced by the present specification, would have been reasonably apprised of the criteria for assessing the extent of suppression of initial burst. As such, the present rejection should be withdrawn.

**B. Claim 25**

The rejection reads as follows:

Claim 25 reads "a method of increasing the efficiency of bioactive substance.. ." None of the embodiments taught in the

application specifically define "increasing efficiency" in this context, and there is no means taught for assessing said increase. Therefore, the claim is rejected for failure to establish criteria for assessing improved efficiency of "a method of increasing the efficiency of bioactive substance.. ." in one particular embodiment over another.

Office action, para. 4. Claim 25 currently recites *a method of prolonging the efficiency of an LH-RH derivative* .... It is submitted that one of ordinary skill in the art, as evidenced by the present specification, would have been reasonably apprised of the criteria for assessing the extent of prolongation of *an LH-RH derivative*. See, e.g., Tables 2-3. As such, the present rejection should be withdrawn.

C. ***Claim 26***

The rejection reads as follows:

Claim 26 lacks a transitional phrase such as "consisting of," "comprising," "consisting essentially of" or "having" to clarify the scope of a claim when joined with the preamble and body of the claim. Specifically, said phrases in proper context place limits on any unrecited additional components or steps that might be read into a claim. Lacking said transitional phrase the claim is rendered indefinite.

Office action, para. 4. It is respectfully submitted that a transitional phrase is not required.

There is no requirement for a claim to contain a transitional phrase, even though many claims do contain them. Consider, for example, a claim reading "We claim ... An mRNA of the [DNA] SEQ. ID. NO. 1." Even though this claim lacks a transition phrase/word, there is absolutely nothing ambiguous about such a claim, as long as SEQ. ID. NO. 1 is defined to the extent that would reasonably apprise one of ordinary skill in the art of its meaning so that one of ordinary skill in the art could determine the corresponding mRNA.

Such is the case here, where claim 26 reads: "A hydroxynaphthoate of an LH-RH derivative." Even though this claim lacks a transition phrase/word, there is absolutely nothing ambiguous about claim 26, because the term LH-RH derivative would reasonably apprise one of ordinary skill in the art of its meaning so that one of ordinary skill in the art

could determine the corresponding hydroxynaphthoate. As such, the present rejection should be withdrawn.

**V. Rejection Under 35 U.S.C. § 112, first paragraph (Enablement, claim scope)**

Claims 17-20, 24-25, and 28 are rejected under 35 U.S.C. § 112, first paragraph, because “the specification, while being enabling for examples disclosed therein (p. 42, l. 25 - p. 46, l. 20), does not reasonably provide enablement for the breadth of the claimed invention.” Office action, para. 6. The present version of the claims avoids this rejection, as they were amended to recite the enabled subject matter, e.g., see Experimental Examples 3-4. Thus, the present rejection should be withdrawn.

**VI. Rejection Under 35 U.S.C. § 102(b)**

Claims 26-28 are rejected under 35 U.S.C. § 102(b) as being anticipated by El-Naggar, et al. Office action, para. 8. The rejection reads as follows:

The claims are directed to non-specific peptides and their hydroxynaphthoate derivatives. El-Naggar et al. teaches the syntheses of several examples of such compounds (see entire reference, especially Table 1). Therefore, the claimed invention is anticipated by El-Naggar et al.

Office action, para. 8 (rejection’s formatting was changed).

A reference cannot anticipate what it fails to describe. Here, the present version of the claims was amended to change the term “bioactive peptide” to --an LH-RH derivative--. El-Naggar et al. neither teaches nor suggests an embodiment of the amended claims. Thus, the present version of the claims avoids this issue, and the rejection should be withdrawn.

**VII. Rejection Under 35 U.S.C. § 103(a)**

Claims 17-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jaffe (U.S. Pat. No. 4,272,398). The rejection reads as follows:

The claims are directed to production of a solid controlled release dosage form comprising a biologically active substance, excipients and a biodegradable polymer. The process involves dissolution of the ingredients in organic solvent, followed by treatment with an aqueous solution.

Jaffe teaches a micro-encapsulation process that yields a solid dosage form wherein the active ingredient and other formulation components are uniformly dispersed in a biodegradable polymer. The process comprises dissolving the formulation components and biodegradable polymer in a suitable organic solvent, then dispersing the resulting solution in aqueous medium. After evaporation of the organic solvent, the resulting solid mass can be formed into a capsule or tablet. Particle size and plasticity of the solid mass are controllable; thus release of the active ingredient from the biodegradable polymer matrix is controllable.

Thus, the claimed invention is *prima facie* obvious of Jaffe.

Office action, para. 10. The rejection uses a *per se* line of reasoning, an approach explicitly forbidden over a decade ago. In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995); In re Brouwer, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996). None of the references relied upon by the Examiner teaches or suggests an embodiment of the amended claims. Thus, the present version of the claims avoids this issue, and the rejection should be withdrawn.

### **CONCLUSION**

It is believed that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.


The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5569  
Facsimile: (202) 672-5399

By  (45,943)  
SEAN A. PASSINO  
Stephen B. Maebius  
Attorney for Applicants  
Registration No. 35,264  
For

Enclosures: Substitute Specification and Marked-Up Copy.